REMARKS/ARGUMENTS

The rejections presented in the Office Action dated September 19, 2007 (hereinafter Office Action) have been considered. Claims 1-16 and 18-62 remain pending in the application. Reconsideration of the pending claims and allowance of the application in view of the present response is respectfully requested.

Claims 1, 15, 21, 31, 37, and 50 have been amended. Support for the amendments to claims 1, 21, 37, and 50 can be found in the subject matter canceled from claim 17 and from Page 37, Lines 19-25 of the Specification, among other locations. Support for the amendments to claims 15 and 31 can be found on Page 24, Lines 10-20 of the Provisional Application incorporated by reference on Page 1 of the current Application. Accordingly, no new matter has been added.

Claims 1-5, 8, 13-14, 19-25, 28-29, 33-41, 44, 47-54, 57, and 60-62 are rejected based on 35 U.S.C. §103(a) as being unpatentable over U.S. Publication No. 2002/0035376 by *Bardy et al.* (hereinafter "*Bardy'376*") in view of U.S. Publication No. 2002/0082658 by *Heinrich* (hereinafter "*Heinrich*"). Claims 1-5, 8, 13-25, 28-41, 44, 47-54, 57, and 60-62 are rejected based on 35 U.S.C. §102(a) as being anticipated by U.S. Publication No. 2002/0091414 by *Bardy et al.* (hereinafter "*Bardy'414*") in view of *Heinrich.*

The Applicant's independent claims 1, 21, 37, and 50 each recite, among other features, some variation of therapy instructions stored in the energy delivery circuitry, the therapy instructions executable to direct delivery of the tachycardia therapy, the bradycardia therapy, and the asystole prevention therapy, the asystole prevention therapy comprising a pacing rate lower than that associated with the bradycardia therapy and 20 pulses per minute or less. The Applicant respectfully submits that *Bardy'376* fails to disclose at least a tachycardia therapy, a bradycardia therapy, and an asystole prevention therapy, the asystole prevention therapy comprising a pacing rate lower than that associated with the bradycardia therapy and 20 pulses per minute or less, even in combination with *Heinrich.*

The Office Action relies on each of *Bardy'376* and *Bardy'414* to teach or suggest a tachycardia therapy and a bradycardia therapy (Pages 3 and 8). The Office Action acknowledges that "Bardy fails to specifically teach detecting an asystole condition and

[that] the asystole prevention therapy is delivered upon detection of the asystole condition," and relies upon *Heinrich* to provide the subject matter missing from *Bardy'376* and *Bardy'414*. (*Id.*).

Heinrich discloses "delivery of acute tachyarrhythmia and bradyarrhythmia therapy using a subcutaneous stimulation device." ([0001]). *Heinrich* discloses using this bradyarrhythmia therapy in response to detecting a period of asystole. ([0064], [0066], and [0067]). Considering that bradycardia and bradyarrhythmia are essentially the same condition ([0003]), the Applicant respectfully submits that *Heinrich* does not disclose using an asystole therapy that is different from bradycardia therapy. Rather, *Heinrich* discloses delivering bradycardia therapy in response to detection of a period of asystole.

The Applicant notes that the 1500 millisecond pacing interval of *Heinrich's* bradyarrhythmia places the pacing rate of the therapy at 40 pulses per minute [0067], which is greater than that of the asystole prevention therapy, which is claimed as 20 pulses per minute or less (*See* claims 1, 21, 37, and 50).

As such, the combinations of *Bardy'376* and *Heinrich* and *Bardy'414* and *Heinrich* each disclose two therapies (tachycardia therapy and bradycardia therapy) deliverable for three conditions (detection of tachycardia, bradycardia, and asystole), the bradycardia therapy being delivered for both bradycardia and asystole conditions.

The combinations of *Bardy'376* and *Heinrich* and *Bardy'414* and *Heinrich* do not disclose a tachycardia therapy, the bradycardia therapy, and the asystole prevention therapy, the asystole prevention therapy comprising a pacing rate lower than that associated with the bradycardia therapy and 20 pulses per minute or less. Therefore, each of the combinations of *Bardy'376* and *Heinrich* and *Bardy'414* and *Heinrich* fails to teach or suggest each and every element and limitation of independent claims 1, 21, 37, and 50, and cannot render these claims obvious.

The Office Action identifies bradycardia therapy pacing parameters of *Bardy'414* in addressing claims 15, 16, 18, and 30-32, each of which concerns some aspect of the asystole prevention therapy. (Page 12). The Applicant notes that the Office Action relies on *Heinrich* to address the aspects of the claims related to asystole prevention therapy because

Bardy'414 does not disclose an asystole prevention therapy, as acknowledged in the Office Action. (Page 8). The Applicant respectfully submits that this further underscores the deficiency of the combination of *Bardy'414* and *Heinrich* in teaching or suggesting the claimed limitation – the combination only discloses tachycardia and bradycardia therapies for treating tachycardia, bradycardia, and asystole, and does not disclose each of a tachycardia therapy, bradycardia therapy, and an asystole prevention therapy.

Each of claims 2-5, 8, 13-20, 22-25, 28-36, 38-41, 44, 47-49, 51-54, 57, and 60-62 depend from one of independent claims 1, 21, 37, and 50, respectively. While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 21, 37, and 50. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Moreover, if an independent claim is nonobvious under 35 U.S.C. §103, then any claim depending therefrom is nonobvious. (*In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)). Therefore, dependent claims 2-5, 8, 13-20, 22-25, 28-36, 38-41, 44, 47-49, 51-54, 57, and 60-62 are not made obvious by *Bardy'376* or *Bardy'414,* even in combination with *Heinrich.*

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 1-5, 8, 13-25, 28-41, 44, 47-54, 57, and 60-62 and notification that these claims are in condition for allowance.

Claims 6, 26, 42, and 55 are rejected based on 35 U.S.C. §103(a) as being unpatentable over *Bardy'376* in view of *Heinrich* as applied to claims 1, 21, 37, and 50 and further in view of U.S. Patent No. 4,562,841 to *Brockway et al.* (hereinafter "*Brockway*"). Claims 6, 26, 42, and 55 are rejected based on 35 U.S.C. §103(a) as being unpatentable over *Bardy'414* in view of *Heinrich* as applied to claims 1, 21, 37, and 50 and further in view of *Brockway.*

Each of claims 6, 26, 42, and 55 depend from one of independent claims 1, 21, 37, and 50, respectively. While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the

remarks made in connection with independent claims 1, 21, 37, and 50. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, consistent with *In re Fine*, dependent claims 6, 26, 42, and 55 are not made obvious by *Bardy'376* or *Bardy'414,* in combination with *Heinrich*, even in view of *Brockway*.

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 6, 26, 42, and 55 and notification that these claims are in condition for allowance.

Claims 7, 27, 43, and 56 are rejected based on 35 U.S.C. §103(a) as being unpatentable over *Bardy'376* in view of *Heinrich* as applied to claims 1, 21, 37 and 50 and further in view of U.S. Patent No. 5,814,079 to *Kieval et al.* (hereinafter "*Kieval*"). Claims 7, 27, 43, and 56 are rejected based on 35 U.S.C. §103(a) as being unpatentable over *Bardy'414* in view of *Heinrich* as applied to claims 1, 21, 37, and 50 and further in view of *Kieval*.

Each of claims 7, 27, 43, and 56 depend from one of independent claims 1, 21, 37, and 50, respectively. While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1, 21, 37, and 50. These dependent claims include all of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, consistent with *In re Fine*, dependent claims 7, 27, 43, and 56 are not made obvious by *Bardy'376* or *Bardy'414,* in combination with *Heinrich*, even in view of *Kieval.*

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 7, 27, 43, and 56 and notification that these claims are in condition for allowance.

Claims 17-18 and 31-32 are rejected based on 35 U.S.C. §103(a) as being unpatentable over *Bardy'376* in view of *Heinrich* as applied to claims 1 and 21.

In addressing claims 18, 31, and 32, the Office Action alleges that:

> It would have been an obvious design choice to one with ordinary skill in the art at the time of the invention to provide an asystole prevention therapy comprising delivery of pacing pulses at a fixed or variable rate lower than a pacing rate associated with the bradycardia therapy, since applicant has not disclosed that this lower rate provides any criticality and/or unexpected results and it appears that the invention would perform equally well with any pacing rate such as the pacing rate taught by Bardy and Heinrich for treating asystole and bradycardia. (Page 16).

The Applicant respectfully disagrees. For example, the Applicant's Specification states, in discussion asystole prevention therapy, that:

> Pacing, in this regard, is provided only as a means to maintain patient life post shock during asystole. The maximum pacing interval is preferably short enough to maintain life, but sufficiently long enough to not enable full consciousness in the patient where pacing could be perceived as particularly painful. (Page 37, Lines 19-22).

Accordingly, the Applicant respectfully submits that criticality is disclosed for the three pacing therapies, including having a unique asystole prevention therapy with a goal different from that of *Bardy'376* and *Heinrich's* bradycardia pacing therapy, and different parameters to meet the different goal. For example, *Heinrich's* bradyarrhythmia therapy attempts to establish the "re-occurrence of the patient's intrinsic normal heart beat." ([0067]; emphasis added). In at least this way, the asystole prevention therapy is not merely an obvious design choice in light of *Bardy'376* and *Heinrich's* bradycardia therapy.

Each of claims 17-18 and 31-32 depend from one of independent claims 1 and 21, respectively. While the Applicant does not acquiesce to the particular rejections to these dependent claims, it is believed that these rejections are now moot in view of the remarks made in connection with independent claims 1 and 21. These dependent claims include all

of the limitations of the base claim and any intervening claims, and recite additional features which further distinguish these claims from the cited references. Therefore, consistent with *In re Fine*, dependent claims 17-18 and 31-32 are not made obvious by *Bardy'376* or *Bardy'414,* even in combination with *Heinrich.*

As such, the Applicant respectfully requests withdrawal of the §103(a) rejection of claims 17-18 and 31-32 and notification that these claims are in condition for allowance.

It is to be understood that the Applicant does not acquiesce to the Examiner's characterization of the asserted art or the Applicant's claimed subject matter, nor of the Examiner's application of the asserted art or combinations thereof to the Applicant's claimed subject matter. Moreover, the Applicant does not acquiesce to any explicit or implicit statements or conclusions by the Examiner concerning what would have been obvious to one of ordinary skill in the art, what is equivalent structure, and obvious design choices. The Applicant respectfully submits that a detailed discussion of each of the Examiner's rejections beyond that provided above is not necessary, in view of the clear absence of teaching and suggestion of various features recited in the Applicant's pending claims. The Applicant, however, reserves the right to address in detail the Examiner's characterizations, conclusions, and rejections in the future.

Authorization is given to charge Deposit Account No. 50-3581 (GUID.611PA) any necessary fees for this filing. If the Examiner believes it necessary or helpful, the Examiner is invited to contact the undersigned attorney to discuss any issues related to this case.

Respectfully submitted,

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